

007 2 2 1997

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Albertus J. M. Schrijver
Manager Research Centre
Bejo Zaden BV
P.O. Box 50
Trambaan 1
1749 ZH Warmenhuizen
The Netherlands

Dear Mr. Schrijver:

This is in regard to your genetically modified radicchio rosso about which you initiated consultations with the agency on May 20, 1997. According to Bejo Zaden, the new radicchio varieties have been modified for male sterility through anther-specific expression of the *barnase* gene derived from *Bacillus amyloliquefaciens*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new radicchio varieties on May 20, 1997. These communications informed FDA of the steps taken by Bejo Zaden to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Bejo Zaden has concluded that the new radicchio varieties are not materially different in composition, safety, or other relevant parameters from radicchio currently on the market, and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF0045 and that will be maintained in the Office of Premarket Approval.

Based on the information Bejo Zaden has presented to FDA, we have no further questions concerning the transgenic male sterile radicchio rosso lines, RM3-3, RM3-4 and RM3-6, at this time. However, as you are aware, it is Bejo Zaden's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-13, HFS-200, HFS-205, HFS-206, HFS-225, HFS-226, HFS-246, HFS-247,
HFV-200, HFV-221, HFV-199, HFV-228, BNF45